

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Koji Yamada, et al.

Serial No. 10/571,861

Filed: March 14, 2006

For: NOVEL INDOLOPYRROLOCARBAZOLE DERIVATIVE  
WITH ANTITUMOR ACTIVITYArt Unit: To be determinedExaminer: To be determinedCommissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97**

Sir:

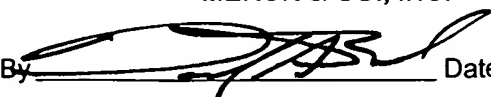
1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

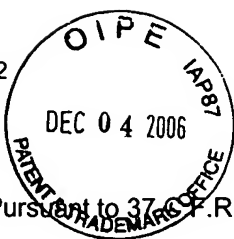
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

**MERCK & CO., INC.**By  Date 11/30/06



## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: David A. Muthard

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 35,297

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-3903

Date: 11/30/06



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Koji Yamada, et al.

Serial No.: 10/571,861 Case No.: BY0028P

Filed: March 14, 2006

For: NOVEL INDOLOPYRROLOCARBAZOLE  
DERIVATIVE WITH ANTITUMOR ACTIVITY

Art Unit:  
To be determined

Examiner:  
To be determined

Commissioner of Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

EXPLANATION OF RELEVANCE OF NON-ENGLISH DOCUMENTS UNDER 37  
C.F.R. 1.98(a)(3)(i)

Sir:

Applicants respectfully note that three (3) of the documents listed on the USPTO 1449 for submitted herewith is not in the English language and a copy of an English translations of that documents is not within the possession, custody or control of Applicants, and, to the Applicants knowledge, is not readily available. Below is a concise explanation of the relevance of those non-English documents:

The Japanese patent publication JP 6-128283 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted amine substituent on the amine of the fused carbazole dione ring. The compounds disclosed therein are described as anti-tumor compounds. There is no specific disclosure in the JP 6-128283 publication of pyridylalkylamine, furylalkylamine or thienylalkylamine substituents on the amine of the fused carbazol dione ring.

The PCT patent publication WO96/04293 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted amine substituent on the amine of the fused carbazole dione ring. The compounds disclosed therein are described as anti-tumor compounds. There is no specific disclosure in the WO96/04293 publication of pyridylalkylamine, furylalkylamine or thienylalkylamine substituents on the amine of the fused carbazol dione ring.

The Japanese patent publication JP 10-245390 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted

aryl/heteroaryl alkylamine substituent on the amine of the fused carbazole dione ring. The substituted aryl/heteroaryl group is selected from substituted phenyl, substituted pyridyl, substituted furyl, substituted naphthyl and substituted thienyl. The compounds disclosed therein are described as anti-tumor compounds.

The instant invention discloses novel 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having substituted and unsubstituted aryl/heterocyclyl alkoxy/alkyl/alkyl amino substituents on the amine of the fused carbazol dione ring. Several classes of such substituents are specifically excluded from the scope of the generic claims.

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS  
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DATE APPEARING BELOW.

MERCK & CO., INC.

BY: 

DATE: 11/30/06

Respectfully submitted,

By: 

David A. Muthard

Reg. No. 35,297

Attorney for Applicant(s)

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Rahway, New Jersey 07065-0907

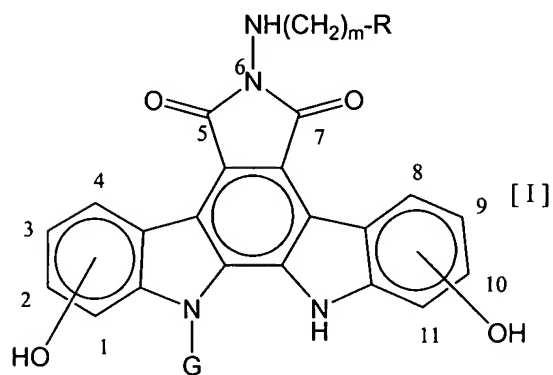
(732) 594-3903

Date: November 30, 2006



**Main Claim of the Japanese Patent Application (Serial No. JP97-61875) as originally filed**

A compound represented by the formula:



wherein **R** represents a phenyl group, naphthyl group, pyridyl group, furyl group, thienyl group each of which has one or two substituents selected from the group consisting of a hydroxyl group, a lower alkoxy group, a hydroxyl lower alkyl group, and a hydroxyl lower alkenyl group, except that when the phenyl group, naphthyl group, pyridyl group, furyl group, or thienyl group has a lower alkoxy group as a substituent, each of which simultaneously has another substituent selected from the group consisting of a hydroxyl group, a lower alkoxy group, a hydroxyl lower alkyl group and a hydroxyl lower alkenyl group;

**m** represents an integer of 1 to 3;

**G** represents a  $\beta$ -D-glucopyranosyl group; and the positions of substitution of the hydroxyl groups on the indolopyrrolo[1,2-a]carbazole ring are the 1- and 11-positions, or the 2- and 10-positions,

or a pharmaceutically acceptable salt thereof.

# STATEMENT BY APPLICANT

(use ~~as~~ many sheets as necessary)

Sheet

**1**

of

2

**COMPLETE IF KNOWN**

Application Number

10/571,861

**Filing Date**

March 14, 2006

**First Named Inventor**

**Koji Yamada**

## Group Art Unit

**To be determined**

Examiner Name

**To be determined**

Attorney Docket Number

BY0028P

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
		PCT	WO 2002/036601		Merck & Co., Inc.	05/10/2002
		PCT	WO 1996/004293		Banyu Pharmaceutical Co., Ltd.	02/15/1996
		JPO	JP 6-128283		Banyu Pharmaceutical Co., Ltd.	05/10/1994
		JPO	JP 10-245390		Banyu Pharmaceutical Co., Ltd.	09/14/1998

Examiner  
Signature

Date  
Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**SEND TO:** Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 8/24/2006

Substitute for form 1449B/PTO

## STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

**COMPLETE IF KNOWN****Application Number**

10/571,861

**Filing Date**

March 14, 2006

**First Named Inventor**

**Koji Yamada**

**Group Art Unit**

**To be determined**

**Examiner Name**

To be determined

Attorney Docket Number

**BY0028P**

## NON PATENT LITERATURE DOCUMENTS

Examiner  
Initials\*Cite  
No.

**Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.**

**Examiner  
Signature**

Date  
Considered